



General

Guideline Title

Clinical policy: critical issues in the prescribing of opioids for adult patients in the emergency department.

Bibliographic Source(s)

Cantrill SV, Brown MD, Carlisle RJ, Delaney KA, Hays DP, Nelson LS, O'Connor RE, Papa A, Sporer KA, Todd KH. Clinical policy: critical issues in the prescribing of opioids for adult patients in the emergency department. Ann Emerg Med. 2012 Oct;60(4):499-525. [79 references] PubMed

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

March 22, 2016 – Opioid pain medicines
 : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Definitions for the strength of evidence (Class I-III) and strength of recommendations (Level A-C) are repeated at the end of the Major Recommendations.

1. In the adult Emergency Department (ED) patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse?

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. The use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

2. In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications? *Level A recommendations*. None specified.

Level B recommendations. None specified.

Level C recommendations.

- 1. For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether nonopioid analgesics and nonpharmacologic therapies will be adequate for initial pain management.
- Given a lack of demonstrated evidence of superior efficacy of either opioid or nonopioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.
- 3. If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (e.g., <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.
- 3. In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids?

Level A recommendations. None specified.

Level B recommendations. For the short-term relief of acute musculoskeletal pain, emergency physicians may prescribe short-acting opioids such as oxycodone or hydrocodone products while considering the benefits and risks for the individual patient.

Level C recommendations. Research evidence to support superior pain relief for short-acting schedule II over schedule III opioids is inadequate.

4. In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations.

- 1. Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic noncancer pain seen in the ED.
- 2. If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.
- 3. The clinician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs.

Definitions:

Strength of Evidence

Literature Classification Schema*

Design/Class	Therapy †	Diagnosis ‡	Prognosis §
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series	Case series	Case series

Design/Class	Therapy † Case report	Diagnosis ‡ Case report	Prognosis § Case report
	Other (e.g., consensus, review)	Other (e.g., consensus, review)	Other (e.g., consensus, review)

^{*}Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

- ‡ Objective is to determine the sensitivity and specificity of diagnostic tests.
- § Objective is to predict outcome, including mortality and morbidity.

Approach to Downgrading Strength of Evidence*

	Design/Class		
Downgrading	1	2	3
None	I	П	III
1 Level	II	Ш	X
2 Levels	Ш	X	X
Fatally Flawed	X	X	X

^{*}See the "Description of Methods Used to Analyze the Evidence" field for more information.

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

Level C recommendations. Other strategies for patient management that are based on Class III studies, or in the absence of any published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Acute noncancer pain
- Acute exacerbation of noncancer chronic pain

[†] Objective is to measure therapeutic efficacy comparing interventions.

Management Treatment Clinical Specialty Emergency Medicine Family Practice Internal Medicine **Intended Users** Hospitals Nurses Physicians Guideline Objective(s) • To provide evidence-based recommendations for prescribing short-acting opioids for adult emergency department (ED) patients with painful acute or chronic conditions while attempting to address the increasing frequency of adverse events, abuse, and overdose of prescribed opioid analgesics To address the following critical questions: • In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse? • In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications? • In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are shortacting schedule II opioids more effective than short-acting schedule III opioids? • In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from

Target Population

Guideline Category

Evaluation

Adult patients presenting to the emergency department with acute noncancer pain or an acute exacerbation of chronic noncancer pain

Note: This guideline is not intended to address the long-term care of patients with cancer or chronic noncancer pain.

Interventions and Practices Considered

the ED outweigh the potential harms?

- 1. Use of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse
- 2. Consideration of opioids versus nonopioid analgesics and nonpharmacologic therapies during acute phase
- 3. Consideration of short-acting schedule II opioids versus short-acting schedule III opioids for new onset acute pain
- 4. Consideration of the benefits of prescribing opioids at discharge from the emergency department versus the potential harms

- Pain relief
- Functional outcome
- Adverse effects
- · Opioid-related deaths
- Misuse, abuse, and diversion of prescription drugs

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Searches of MEDLINE, MEDLINE InProcess, and the Cochrane Library were performed. All searches were limited to English-language sources, human studies, adults, and years 2000 to 2011. Specific key words/phrases and years used in the searches are identified under each critical question (see original guideline document). In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members were included.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence

Literature Classification Schema*

Design/Class	Therapy †	Diagnosis ‡	Prognosis §
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
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	Case report	Case report	Case report
	Other (e.g., consensus, review)	Other (e.g., consensus, review)	Other (e.g., consensus, review)

^{*}Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

- † Objective is to measure therapeutic efficacy comparing interventions.
- ‡ Objective is to determine the sensitivity and specificity of diagnostic tests.
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Approach to Downgrading Strength of Evidence*

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2 Levels	Ш	X	X
Fatally Flawed	X	X	X

^{*}See the "Description of Methods Used to Analyze the Evidence" field for more information.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members for quality and strength of evidence. The articles were classified into 3 classes of evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic studies, respectively (see the "Rating Scheme for the Strength of the Evidence" field). Articles were then graded on dimensions related to the study's methodological features: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (e.g., selection, detection, transfer), external validity (i.e., generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula, taking into account the design and study quality (see the "Rating Scheme for the Strength of the Evidence" field). Articles with fatal flaws or that were not relevant to the critical question were given an "X" grade and were not used in formulating recommendations for this policy. Evidence grading was done with respect to the specific data being extracted and the specific critical question being reviewed. Thus, the level of evidence for any one study may have varied according to the question, and it is possible for a single article to receive different levels of grading as different critical questions were answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of the original guideline document. Evidence grading sheets may be viewed at http://www.acep.org/clinicalpolicies/?pg1

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline is the result of the efforts of the American College of Emergency Physicians, in consultation with the Centers for Disease Control and Prevention, and the Food and Drug Administration.

This policy is a product of the American College of Emergency Physicians (ACEP) clinical policy development process, including expert review, and is based on the literature; when literature was not available, consensus of panel members was used.

Rating Scheme for the Strength of the Recommendations

Clinical findings and strength of recommendations about patient management were made according to the following criteria:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

Level C recommendations. Other strategies for patient management that are based on Class III studies, or in the absence of any adequate published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Expert review comments were received from emergency physicians, toxicologists, pain and addiction medicine specialists, pharmacologists, occupational medicine specialists, and individual members of the American Academy of Clinical Toxicology, American Academy of Family Physicians, American Academy of Pain Medicine, American Chronic Pain Association, American College of Occupational and Environmental Medicine, American College of Osteopathic Emergency Physicians, American College of Physicians, American Pain Society, American Society of Health-System Pharmacists, American Society of Interventional Pain Physicians, Emergency Medicine Resident's Association, and Emergency Nurses Association. Their responses were used to further refine and enhance this policy; however, their responses do not imply endorsement of this clinical policy.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of opioids in adult patients presenting to the emergency department with acute noncancer pain or an acute exacerbation of chronic

Potential Harms

- Prescriptions for opioids should be provided for limited amounts and for a limited period. Extra caution (such as use of prescription drug
 monitoring programs and seeking of collateral patient information such as patient visit history) may be indicated for patients identified as
 possibly having an increased risk for substance dependence or abuse.
- Potential decreased patient satisfaction in receiving alternative to opioid for pain relief.

Qualifying Statements

Qualifying Statements

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry, or the Food and Drug Administration.
- Policy statements and clinical policies are the official policies of the American College of Emergency Physicians (ACEP) and, as such, are
 not subject to the same peer review process as articles appearing in the print journal. Policy statements and clinical policies of ACEP do not
 necessarily reflect the policies and beliefs of Annals of Emergency Medicine and its editors.
- This policy is not intended to be a complete manual on the evaluation and management of adult emergency department patients with painful
 conditions where prescriptions for opioids are being considered, but rather is a focused examination of critical issues that have particular
 relevance to the current practice of emergency medicine.
- Recommendations offered in this policy are not intended to represent the only management options that the emergency physician should
 consider. The ACEP clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician
 those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Oct

Guideline Developer(s)

American College of Emergency Physicians - Medical Specialty Society

Source(s) of Funding

This clinical policy was funded under contract 200-2011-M-38670 with the Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury.

Guideline Committee

American College of Emergency Physicians Opioid Guideline Writing Panel

Composition of Group That Authored the Guideline

Writing Panel: Stephen V. Cantrill, MD (Chair); Michael D. Brown, MD, MSc (Methodologist); Russell J. Carlisle, MD; Kathleen A. Delaney, MD; Daniel P. Hays, PharmD, BCPS; Lewis S. Nelson, MD; Robert E. O'Connor, MD, MPH (ACEP Board Liaison); AnnMarie Papa, DNP, RN, CEN, NE-BC (ENA Representative); Karl A. Sporer, MD; Knox H. Todd, MD, MPH

Financial Disclosures/Conflicts of Interest

Relevant industry relationships/potential conflicts of interest:

Dr. Sporer is a consultant to Alcomed, a pharmaceutical company. Dr. Todd serves on the Professional Advisory Board of the American Chronic Pain Association and has previously been a consultant to the pharmaceutical industry.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical questions.

Guideline Endorser(s) Emergency Nurses Association - Professional Association Guideline Status This is the current release of the guideline. Guideline Availability Electronic copies: Available in Portable Document Format (PDF) from the American College of Emergency Physicians (ACEP) Web site ACEP clinical policies are available for mobile applications at the ACEP Web site Availability of Companion Documents None available Patient Resources None available **NGC Status** This NGC summary was completed by ECRI Institute on November 5, 2012. The information was verified by the guideline developer on December 5, 2012. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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